

Appl. No. 09/787,922  
Amendment dated: November 26, 2007  
Reply to OA of: March 22, 2007

### **REMARKS**

Applicants have further amended the claims to more particularly define the invention taking into consideration the outstanding Final Rejection. Claims 1 and 40 have been amended to specify a foam slip as fully supported by the specification as originally filed. Claim 26 has been amended to change the dependency for clarification. Additionally, on page 8 of the present specification Applicants state that it is preferable that the amount of ceramic particulate when mill-foaming the ceramic slip is from 3 to 20 w/w% ceramic particulate to the milling media (more preferably from 5 to 15 w/w% ceramic particulate to the milling media). Claim 23 has been amended to include the first indicated range and claim 41 has been added containing this limitation but dependent on claim 40. Entry of the claims as now amended, creating new issues, is in order in view of the filing herewith of an RCE.

The objection to claims 17-19 under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim has been carefully considered but is most respectfully traversed in view of the amendments to the claims and further in view of the following comments. Claim 17 is a dependent claim which depends on claim 1. Claims 18 and 19 are dependent on claim 17. Claim 1 is an open claim because of the use of the term comprises, a variation of comprising, and therefore may contain additional steps. In this regard, please see MPEP§ 2111.03 which states that the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended.").< *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended

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and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.)

In the Official Action it is urged, on page 2, that, "Claim 17 requires evaporating the carrier prior to the burn-out. But claim 1 requires burn-out of the slip". These statements are most respectfully traversed as they do not represent a reasonable interpretation of the claims as would be appreciated by one of ordinary skill in the art to which the invention pertains. As would be evident to one of ordinary skill in the art to which the invention pertains, claim 1 includes an initial formation of a slip which is then converted to a foam slip in a ball mill which is then removed from the ball mill and cast into a mold, injected, cast on a flat surface, etc. That is, the foamed slip includes a binder and has sufficient integrity to maintain the structure of a foam, even though it contains solvent. The foam is then treated to form a synthetic bone material, which may include various drying stages prior to burn-out as would be appreciated by one of ordinary skill in the art.

Moreover, it should be noted that claim 17 does not recite that all of the liquid carrier has to be evaporated. As a consequence, Applicants do not consider that claim 17 is limited solely to a casting. Claim 17 provides that prior to burn-out of the organic binder, the liquid carrier is allowed to evaporate from the foamed carrier slip. This requires a further step which may be included in claim 1 as an open claim but is not specifically recited therein. Therefore claim 17 clearly limits claim 1 and is a proper dependent claim. See also page 9, lines 12 to 15 and as noted at the top of page 10, the foamed slip can be cast into a mold or unrestrained onto a flat surface or injected. Accordingly, it is most respectfully requested that this objection be withdrawn.

The rejection of claims 1, 2, 4-16, 20-27, 33 and 35-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which Applicants regard as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims and further in view of the following comments.

The only claims specifically mentioned in the body of the rejection are claims 4, 7, 10, and 12-16. The appropriate claims have been amended to conform the claim language with the proper Markush terminology by use of the language, "consisting of ... and", in the claims. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

With respect to claim 7, AW glass-ceramic stands for Apatite-Wollastonite glass-ceramic as would be appreciated by one of ordinary skill in the art to which the invention pertains. This is a well-known biomaterial and Applicants submit herewith copies of references in support of their argument that one of ordinary skill in the art would know the meaning of this term. Applicants believe that they have met the burden of proof in this area. Clarification as to the requirement of the EAST system would appreciate in the next Official Action if this rejection is maintained.

The Examiner objects to the term "w/v %" with respect to claim 12 and states that this term indefinite as to its meaning. It is further stated that it is unclear if the "/" means "or" as it does in claim 4. Applicants submit that "w/v %" refers to percentage solution and the "/" stands for per and not or. For example, a 1% solution would have 1g of solute dissolved in a final volume of 100ml of solvent. Applicants submit herewith the Wikipedia definition as reference, which states "In biology percentage solutions are often referred to molar ones. A 1% solution would have 1 g of solute dissolved in a final volume of 100 ml of solvent. This would be labelled as a weight/volume [w/v] percentage solution..." The weight is in grams (g) and the volume is in millilitres (ml). This is clearly described in the Examples (see Example 1 on page 16 of Applicants' specification). Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1, 4 -27, 32, 33 and 35-39 under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims,

reasons already of record and the following comments.

Amended claim 1 is directed to a method of producing a synthetic bone material for use in biomedical applications, the synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores with a modal diameter  $d_{\text{mode}} \geq 100 \mu\text{m}$  (see the text on page 4, lines 14 to 17) using a ball mill for foaming. It is clear that WO 93/04013 achieves foaming by the injection of gas into the dispersion. Accordingly, claim 1 differs from WO 93/04013 by virtue of at least the feature of foaming the ceramic slip using a ball mill and also in that the ceramic foam is a macroporous ceramic foam for use in biomedical applications having an open foam structure containing pores with a modal diameter  $d_{\text{mode}} \geq 100 \mu\text{m}$ . It is further noted that the method according to the primary reference does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as required by the claims now present in the application. For this purpose, the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size  $\geq 100 \mu\text{m}$ . That is, the process steps provide the necessary control to obtain the specified degree of porosity. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in Examples II, III and IV of the primary reference would be expected by one of ordinary skill in the art to result in pores having a similar size to that of the filter, i.e. 10 to 16  $\mu\text{m}$ .

Example VIII teaches a slip of hydroxyapatite wherein the product had a mean pore diameter of 24  $\mu\text{m}$ . Moreover, the primary reference states that the pores may be closed and/or the porosity may be open at page 11, second full paragraph. There is no positive teaching in the primary reference of the open pore structure which is a claim limitation of all of the claims now present in the application. Applicants' specification may not be used as a teaching reference.

Applicants note that the primary reference does refer to gas entrapment by mechanical means and suggests that this may be achieved simply by stirring. This is exemplified in Examples V-X, where a paddle stirrer or stirring in a beaker was used.

The other Examples (Example I-IV) rely on a Buchner funnel to produce the foam. It is therefore clear that one of ordinary skill in the art would appreciate that the primary reference had identified what it considered to be suitable methods for forming a foamed ceramic. There is no indication in the primary reference that there were any problems associated with these foaming methods. Accordingly, there simply would not be any motivation for a person skilled in the art to look elsewhere for an alternative foaming technique.

Claim 1 is further limited in that the step of foaming the ceramic slip in step (b) is carried out using a ball mill. The importance of the properties of the synthetic bone material achieved by ball milling in accordance with the claims on appeal is described in Applicants' specification and is not suggested in the prior art relied upon in the rejection. As discussed on pages 8, 9 and 21 of Applicants' specification, the advantages of the presently claimed invention enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip. Thus, the use of a ball mill is a specific aspect of the invention and not simply an equivalent method of foaming the slip.

As noted on page 6 of Applicants' specification the organic binder serves to provide plasticity during forming of the ceramic particulate and green strength in the formed product. It is also noted that all of the examples in Applicants' specification include an organic binder. At page 7, line 5, of Applicants' specification, it is stated that the organic binder will generally be present in a liquid carrier in an amount of from 0.2 to 10 w/v% and more preferably from 0.5 to 6 w/v%. The specific and preferred limitations are specifically set forth in claims 12, 13 and 35. There is absolutely no suggestion in the prior art of these specific ranges which are claim limitations. The

necessary motivation is not in the prior art to suggest these preferred aspects of the presently claimed invention and for this reason, these claims are further distinguished over the prior art.

The only disclosure in the primary reference to the use of a binder is at page 9 which simply suggests that binders such as resins may be included but there is no suggestion of the specified amounts which are clearly indicated to be preferred embodiments of the presently claimed invention. The examples in the primary reference do not use binders let alone suggest the amounts specified in claims 12, 13 and 35. While the '897 patent describes the use of an organic binder in the paragraph beginning at column 3, line 25, this relates to a foam slurry which is produced by mixing an alumina based ceramic powder, SiC whiskers, and a solution containing a dispersant, an organic binder and a foaming agent in water. This in no way suggests a modification of the primary reference to arrive at the presently claimed preferred binder concentrations as claimed in claims 11, 12 and 35.

As discussed at page 20 of Applicants' specification, the results in Table 3 and Figures 7-10 demonstrate how variation in the ratio of ceramic particulate to binder solution variation in both the bulk density (macro-porosity) and the strut density (micro-porosity). The sintered mill-foamed porous ceramics prepared with the greater volume of liquid carrier have lower bulk and strut densities reflecting a more open, interconnected pore structure with large macro-pores and a larger fraction of micro-porosity.

As noted at page 21, the macro-porous ceramic foams according to the present invention have advantages over the prior art cancellous and coral derived materials. The sintered ceramic foam has a bulk porosity in the range of from 70 to 90% as specifically claimed in claim 37 and a slightly broader range in claim 25. These are specific claim limitations which again are in no way suggested by the prior art. The strut density is specified in claims 26 and 38. Clearly, these limitations are present in the claims, discussed in the specification, and further distinguish the claimed subject matter over the prior art.

Claim 1 differs from the teachings of the primary reference for at least the reasons

that this prior art reference does not disclose that the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size  $\geq 100 \mu\text{m}$  and the step of foaming a ceramic slip using a ball mill (step (b)). It is clear that the primary reference achieves foaming by the injection of gas into the dispersion by either mechanical means e.g. stirring or using a filter of defined pore size, see page five, first paragraph of the primary reference.

In an effort to overcome one of the deficiencies of the primary reference, the Final Rejection relies on the teachings of the '897 patent for foaming by ball milling. However, the '897 patent is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. This reference is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. It is, accordingly, clear that US 5,895,897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of WO 93/04013 based on the teaching of US 5,895,897. This absorber has a dense layer provided on the surface of the foamed ceramic, including ceramic fibers as stated at column 2, lines 55-57 which is distinctly different from the structure formed by the process of the present invention as would be appreciated by one of ordinary skill in the art.

It is, accordingly, clear that '897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of the primary reference based on the teaching of the '897 patent related to forming an acoustic absorber to obtain the presently claimed invention. In particular, there is no suggestion in either the primary reference or the '897 patent that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine

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the teachings of the primary reference with the '897 patent, absent Applicants' teaching. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

While in light of the USPTO Examination guidelines for an obviousness determination, one could possibly try a ball mill for foaming, there is no teaching in Oishi et al which suggest this without the presents of a foaming agent. A foaming agent is not used in the presently claimed invention and there is no recognition of the control of the parameters to arrive at the necessary porosity for in accordance with the presently claimed method.

It is further noted that the method according to WO 93/04013 does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as contemplated by the present application. For this purpose, the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size  $\geq 100 \mu\text{m}$ . This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in Examples 2, 3 and 4 of WO 93/04013 would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16  $\mu\text{m}$ .

As already stated, document US 5,895,897 does not disclose a method of producing a synthetic bone material for use in biomedical applications, e.g. for use as a bone graft substitute. There is also no indication that the ceramic according to US 5,895,897 has an open macroporous structure with a modal pore size  $\geq 100 \mu\text{m}$ , as required by claim 1 of the present application. Thus, there would be no motivation for one skilled in the art to combine documents WO 93/04013 and US 5,895,897. There is no indication in either documents that ball milling could or should be used to achieve the required macroporous open foam structure, which is necessary for certain biomedical applications. Indeed this feature is clearly precluded by document WO 93/04013.



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The teaching of Fisher do not suggest that a macroporous open foam structure in accordance with the presently claimed method could be achieved. Therefore, the teachings of this reference does not overcome the deficiencies in the primary reference as discussed above. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants note the statement at the top of page 5 of the Official Action that claim 1 list four steps and that the word, "and" appears between c) and d) and there is no missing conjunction. Therefore, this statement is traversed. However, step d) is an optional step and does not have to be included. The method requires at least three steps and the fact that WO 92/04013 has at least one of the 4 steps does not render the claimed subject matter obvious as discussed above.

The rejection of claims 2, and 40 under 35 U.S.C. §103(a) as being unpatentable over WO 93/04013 in view of Oishi et al, and optionally in view of Fischer as applied to claims 1 and 4-27, 32, 33 and 35-39 above, and further in view of WU has been carefully considered but is most respectfully traversed.

Wu, US 5,656,562, relates to a method of improving the properties of ceramic green bodies. While US 5,656,562 does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, where, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, US 5,656,562 merely describes the conventional technique of using grinding media to mill starting powders. US 5,656,562 is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications. The teachings of this reference does not overcome the deficiencies of the primary reference for reasons discussed above and already of record.

The '562 patent is cited to teach a conventional size of grinding media. However, claim 2 is not concerned with milling powders using a grinding media. Instead, claim 2 is concerned with foaming a ceramic slip in a ball mill. This differs from the teaching of the '562 patent in that the starting material is a ceramic slip (not a starting powder)

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and in that the process produces a foam (not a milled powder). These are fundamental differences as would be appreciated by one of ordinary skill in the art to which the invention pertains. As the Examiner has acknowledged, the '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications. The '562 patent relates to a method of improving the properties of ceramic green bodies. While the '562 patent does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, where, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, the '562 patent merely describes the conventional technique of using grinding media to mill starting powders. The '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

Applicants note that claim 40 defines that the milling media have a diameter in the range of from 10 to 30 mm. While the '562 patent does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam for a synthetic bone material, where the pores have a modal diameter as specified by the claims.

In view of the above comments, it is considered that the disclosure of the '562 patent has been taken out of context and does not establish a prima facie case of obviousness for the claimed subject matter and this rejection should be withdrawn in view of the above comments and further amendments to the claims.

The rejection of claims 2, 40 and 34 under 35 U.S.C. §103(a) as being unpatentable over the primary references as applied to claims 1, 4-27, 32, 33 and 35-39, above, and further in view of Nukada et al US 5,395,722, the '722 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary references. The '722 patent does not overcome the deficiencies of the obviousness rejection as discussed above.

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With regard to the '722 patent, this reference is even further removed relating as it does to a electrophotographic photoreceptor. Even though the '722 patent does mention the use of a ball mill, this is used to prepare (i.e. mill) an organic perylene pigment. The '722 patent has nothing to do with ceramic powders let alone the preparation of a foamed ceramic bone material for biomedical applications.

Additionally, on page 8 of the present specification Applicants state that it is preferable that the amount of ceramic particulate when mill-foaming the ceramic slip is from 3 to 20 w/w% ceramic particulate to the milling media (more preferably from 5 to 15 w/w% ceramic particulate to the milling media). This feature is not taught by WO 93/04013, US 5,895,897 or US 5,656,562. While US 5,395,722 does refer to using 1 to 20 parts by weight milling media to 1 part by weight (organic perylene) pigment (see columns 5, line 68 -Column 6, line 1), Applicants most respectfully submit that this is not relevant to the present case. This is because US 5,395,722 does not use a ball mill to create a ceramic foam. The mill is simply used to grind an organic perylene pigment. There is also a difference in that the perylene pigment in US 5,395,722 is milled in the absence of any liquid carrier. Thus, it is not appropriate to rely on the disclosed range of 1 to 20 parts by weight milling media to 1 part by weight (organic perylene) pigment because our proposed range would refer to the weight of the ceramic particulate when provided in a liquid carrier. In any case, it would be necessary to combine three separate and completely unrelated documents (i.e. WO 93/04013, US 5,656,562, Fisher and US 5,395,722) to even come close to this feature in combination with the features of claim as claimed in claim 40. Moreover, there is absolutely no motivation in the prior art for such a combination. Thus, the combination of references does not render the claimed subject matter prima facie obvious to one of ordinary skill in the art to which the invention pertains. Moreover the resulting properties of the biocompatible material of the present invention are clearly shown as discussed above and the additional publication submitted herewith. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The statement on page 6 of the Final rejection that, "A recitation of the intended

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use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art" is specifically traversed. It is the differences in the process of making which results in the difference in properties of the product which results in the patentability of the claimed process. The specific processing steps of the presently claimed invention distinguishes the claimed invention over the prior art.

The decisions cited by the Examiner in support of the Examiner's holding have been carefully considered but it is most respectfully submitted that they do not support the argument presented. Whether a preamble of intended purpose constitutes a limitation to the claims is, as has long been established, a matter to be determined on the facts of each case in view of the claimed invention as a whole. *In re Duva*, 387 F.2d 402, 407, 156 USPQ 90, 94 (CCPA 1967); *In re Walles*, 366 F.2d 786, 790, 151 USPQ 185, 190 (CCPA 1966). The test in determining whether a claimed invention would have been obvious is what the combined teachings of the references would have suggested to one of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In the present case, the claimed invention is not *prima facie* obvious for the reasons already of record, herein incorporated by reference and the additional amendments to the claims and information submitted herewith.

As stated in MPEP section 2143, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16

USPQ2d at 1432.).

The presently claimed method enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip.

The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity of the biomedical ceramic material to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements for use in the human or animal body.

The present application already provides evidence of the technical advantages associated with using a ball mill to foam the synthetic bone material for biomedical applications (see the Examples and the Figures). In particular, the scanning electron micrographs of the biomedical ceramics presented in the Figures show that using a ball mill to foam the synthetic bone material enables the independent control of the level of total porosity and the level of strut porosity. This may be contrasted with the prior art foaming methods for biomedical applications, which do not achieve this level of control. In this regard, Applicants again note the information sheet of record which provides examples of the prior art foaming methods (e.g. blending, shaking, blowing gas, and gas nucleation) and the typical microstructures of the materials so produced.

With regard to the macroporosity aspect of the microstructure, the conventional method of blending/beating can be seen to result in uni-directional fragmentation of large cells leading to an ellipsoidal pore geometry, which can inhibit the ingress of mesenchymal cells and blood vessels in vivo. The conventional method of shaking can

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result in multi-directional fragmentation of large cells leading to wide pore size distribution and lower interconnection size, which again can inhibit the ingress of mesenchymal cells and blood vessels in vivo. In the conventional method of blowing gas through a slurry, the pore size is determined by slurry viscosity, nozzle diameter and flow rate. It is often difficult to control pore size distribution due to foam coarsening. The conventional method of gas nucleation can result in a non-uniform and non-interconnected microstructure due to pore coarsening caused by the partial pressure of the blowing agent. Finally, in the conventional method of phase burn-out, entrapment of carbon can occur in closed pores, and expansion of the sacrificial phase on burn-out often leads to scaffold micro-fracturing.

In view of the foregoing, the present inventors have found that the conventional foaming methods for preparing biomedical ceramics all have their drawbacks. Moreover, the present inventors have found unexpectedly that the application of a ball mill to foam the ceramic slip results in the controlled development of a mono-modal distribution of well interconnected spherical pores and the independent control of the level of total porosity and the level of strut porosity. This specifically addresses the points raised on page 7 of the final rejection with respect to the advantages in the use of a ball mill. The present inventors have found that the resulting microstructure results in a synthetic biomedical ceramic having improved properties when used in the human or animal body.

Claim 40 recites that the milling media have a diameter in the range of from 10 to 30 mm (and from 15 to 25 mm in claim 34). These ranges are not disclosed in US 5,895,897. While US 5,656,562 does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. Similarly, while US 5,395,722 does mention 1-30 mm milling media, this is for grinding an organic perylene pigment, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam, let alone a ceramic foam for a synthetic bone material for use in the human or animal body, where the pores have a modal diameter  $d(\text{mode})$  of at least 100 microns.

Applicants believe that the present amendment places the application in condition

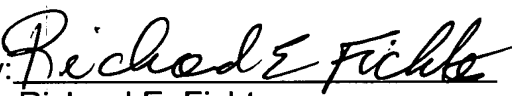
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for allowance. However, if this is not the case, Applicants wish to conduct an interview with the Examiner and would appreciate it very much if the Examiner would be so kind as to contact the undersigned attorney to arrange the interview.

In view of the above comments, further amendments to the claims, and addition documents submitted with the previous response, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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